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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/594,926

04/30/2008

Francesca Levi-Schaffer

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03/30/2011

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EXAMINER

ROONEY, NORA MAUREEN

ART UNIT

PAPER NUMBER

1644

MAIL DATE

DELIVERY MODE

03/30/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 10/594,926 | Applicant(s) LEVI-SCHAFFER ET AL. | |
| | Examiner NORA ROONEY | Art Unit 1644 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 February 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 42-45, 47, 48 and 50-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 42-45, 47, 48 and 50-53 is/are allowed.
- 6) ☒ Claim(s) 52 and 53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>01/10/2011 & 02/02/2011</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendment filed on 02/02/2011 is acknowledged.
2. Claims 42-45, 47-48 and 50-53 are pending and under consideration as they read on bi-specific antibodies and in vivo methods of treating allergic disease.
3. Applicant's IDS documents filed on 01/10/2011 and 02/02/2011 have been considered. The documents on these IDS documents have been considered, though they are crossed off because the documents are not publications with publication dates.
4. The following rejection is necessitated by the amendment filed on 02/02/2011.
5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
6. Claims 52-53 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for: a bi-specific antibody comprising: (i) a, first target recognition component which specifically binds to the inhibitory receptor IRp60; and (ii) a second target recognition component which specifically binds to IgE, cKIT, CCR3, IL-5R or FcRI and a method of treating allergies comprising administering a bi-specific antibody comprising: (i) a, first target recognition component which specifically binds to the inhibitory receptor IRp60; and (ii) a second target recognition component which specifically binds to IgE, cKIT or CCR3, the

specification does not provide reasonable enablement for: a method of **treating an allergy** the method comprising administering to **a subject in need thereof** a therapeutically effective amount of **the bi-specific antibody of claim 42;** and **wherein said disease or condition is allergic asthma.** The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and or use the invention commensurate in scope with these claims for the same reasons as set forth in the Office Action mailed on 10/01/2010.

Applicant's argument filed on 02/02/2011 has been fully considered, but is not persuasive.

Applicant argues:

"While traversing the rejection, but in order to expedite prosecution of this case, Applicant has elected to amend claims 42, 52 and 53 as well as to cancel claims 46, 49 and 54-55 in line with Examiner's opinion of the enabled and supported subject matter, thereby rendering moot the rejection in this case. "

It remains the Examiner's position that the specification has not adequately disclosed that the genus of markers can be used to treat allergic asthma. The art of Munitz et al. (PTO-892; Reference U) teaches that the bi-specific antibody to Irp60 and CCR3 can be used to treat allergic asthma (In particular, whole document). However, as evidenced by the teachings in Munitz et al., allergic asthma is a complex chronic inflammatory disease having many disease components including lung inflammation, mucus production, collagen deposition and peribronchial smooth muscle thickening (In particular, abstract, whole document). There is not

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sufficient evidence to suggest that bi-specific antibodies to Irp60 and IgE, cKIT, IL-5R or FcεR1 are not enabled for the treatment of allergic asthma. The specification is at best enabled for the method of treating allergies comprising administering a bi-specific antibody comprising: (i) a, first target recognition component which specifically binds to the inhibitory receptor IRp60; and (ii) a second target recognition component which specifically binds to IgE, cKIT or CCR3 given the results found in the post-dated art.

Substantiating evidence may be in the form of animal tests, which constitute recognized screening procedures with clear relevance to efficacy in humans. See Ex parte Krepelka, 231 USPQ 746 (Board of Patent Appeals and Interferences 1986) and cases cited therein. Ex parte Maas, 9 USPQ2d 1746.

7. Claims 42-445, 47-48 and 50-51 appear to be in condition for allowance.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nora M. Rooney whose telephone number is (571) 272-9937.

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The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

March 28, 2011

Nora M. Rooney

Patent Examiner

Technology Center 1600

/Nora M Rooney/

Primary Examiner, Art Unit 1644